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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,888	05/24/2001	Kok-Hwee Ng	F4-5733 (1417P-596) (9360	2259

69275 7590 10/03/2007

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EXAMINER	
TOMASZEWSKI, MICHAEL	
ART UNIT	**PAPER NUMBER**
3626	
MAIL DATE	**DELIVERY MODE**
10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/864,888	NG ET AL.	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-84,86-91 and 93-143* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-84, 86-91 and 93-143* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the amendment filed on 7/20/07. Claim 143 has been amended. Claims 49-84, 86-91 and 93-143 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 49-84, 86-91, and 93-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Fletcher et al.* (US 2001/0034614; hereinafter *Fletcher*), in view of *Brierton et al.* (6,234,989; hereinafter *Brierton*).

(A) As per previously presented claim 49, *Fletcher* discloses a system for managing a procedure in a blood component collection facility, the system comprising:

(1) a blood component donor identifier corresponding to a blood component donor (*Fletcher*: par. [0167]);

(2) an operator identifier corresponding to a blood component collection instrument operator (*Fletcher*: par. [0079] and Fig. 6D);

(3) a blood component collection instrument for collecting a blood component from the blood component donor (*Fletcher*: par. [0056]);

(4) a system computer being operably connected to the blood component collection instrument, the system computer running a blood component collection application defining at least one step of a blood component collection process (*Fletcher*: par. [0057] and Fig. 1A); and

(5) an interface having a reader and being operably connected to the system computer for receiving the blood component donor identifier and the operator identifier and transmitting the operator identifier to the system computer proximate the performance of the at least one step of the blood component collection process (*Fletcher*: par. [0057], [0059], [0071], and [0079]; Fig. 6D).

Fletcher, however, fails to expressly disclose a system for managing a procedure in a blood component collection facility, the system comprising:

(6) an interface for receiving arm-prep information from the operator.

Nevertheless, these features are old and well known in the art, as evidenced by *Brierton*. In particular, *Brierton* discloses a system for managing a procedure in a blood component collection facility, the system comprising:

(6) an interface for receiving arm-prep information from the operator (*Brierton*: col. 52, lines 1-27; Fig. 26).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Brierton* with the teachings of *Fletcher* with the motivation of directing an operator through various aspects of blood collection (*Brierton*: abstract).

(B) As per previously presented claim 50, *Fletcher* discloses the system of claim 49, wherein blood component collection application comprises at least one code segment, the at least one code segment selected from a group consisting of a blood component collection initialization code segment (*Fletcher*: par. [0012] and [0069]).

Examiner has noted insofar as claim 50 recites "at least one code segment selected from a group consisting of a blood component collection initialization code segment, an arm-prep code segment, a remove-blood component code segment, and a disconnect-blood-component-donor code segment," a blood component collection initialization code segment has been recited.

(C) As per previously presented claim 51, *Fletcher* discloses the system of claim 49, wherein the blood collection component application associates the blood component donor identifier with the operator identifier (*Fletcher*: par. [0012], [0179] and [0180]; Fig. 6D and 6E).

(D) As per previously presented claim 52, *Fletcher* discloses the system of Claim 51, wherein the reader receives separate input of the blood component donor identifier and the operator identifier from a location proximate the blood component collection instrument (*Fletcher*: par. [0059], [0071] and [0079]).

(E) As per previously presented claim 53, *Fletcher* discloses the system of claim 51, wherein the reader receives separate input of the blood component donor identifier and the operator identifier proximate in time one from the other and prior to blood component collection (*Fletcher*: par. [0059], [0071] and [0079]).

(F) As per previously presented claim 54, *Fletcher* discloses the system of claim 49, wherein the operator identifier is transmitted to the system computer after the performance of the at least one step of the blood component collection process (*Fletcher*: par. [0179]; Fig. 6A-6J).

(G) As per previously presented claim 55, *Fletcher* discloses the system of claim 49, further comprising a second interface operably connected to the system computer, the

second interface for providing access to the data related to the blood component collection process (*Fletcher*: par. [0027] and [0030]).

(H) As per claim 56, *Fletcher* discloses the system of Claim 55, wherein the second interface provides access to at least a portion of the data related to the blood component collection process, the data being received by the second interface in response to a request received by the system computer (*Fletcher*: par. [0027] and [0030]).

(I) As per previously presented claim 57, *Fletcher* discloses the system of claim 55, wherein the second interface provides access to remote blood component collection facility data (*Fletcher*: par. [0012], [0030], and [0033]).

(J) As per previously presented claim 58, *Fletcher* discloses the system of claim 55, wherein the second interface provides access to performance statistics for the blood component collection process (*Fletcher*: par. [0030], [0144], [0155], and [0157]).

(K) As per previously presented claim 59, *Fletcher* discloses the system of claim 55, wherein the second interface provides access to a record of an operator's interaction with the blood component collection facility, the interaction of the operator with the blood component collection facility having been concomitantly logged into the memory for the

blood component collection process by the operator via the interface (*Fletcher*: par. [0019], [0030], [0027], and [0179]).

(L) As per previously presented claim 60, *Fletcher* discloses the system of claim 55, wherein the second interface provides access to information related to the donor (*Fletcher*: par. [0027] and [0030]).

(M) As per previously presented claim 61, *Fletcher* discloses the system of claim 55, wherein the second interface provides access to information related to the blood component collection instrument (*Fletcher*: par. [0027] and [0030]).

(O) As per previously presented claim 62, *Fletcher* discloses the system of claim 55, wherein the second interface provides access to quality assurance statistics of the blood component collection facility (*Fletcher*: par. [0013], [0018], [0027] and [0030]).

(P) As per previously presented claim 63, *Fletcher* discloses the system of claim 55, further comprising an operator identifier wherein the operator utilizes the interface to transmit the operator identifier and the blood component collection kit identifier to the system computer (*Fletcher*: par. [0022], [0057], [0125] and [0179]; Fig. 6A-6D).

(Q) As per previously presented claim 64, *Fletcher* discloses the system of claim 49, further comprising a blood component collection kit for connection to the blood

component collection instrument, the kit having a blood component collection kit identifier (*Fletcher*: par. [0022] and [0125]; Fig. 6A-6D).

(R) As per previously presented claim 65, *Fletcher* discloses the system of claim 49, wherein the blood component collection process further comprises a blood component collection instrument set-up procedure (*Fletcher*: par. [0072] and [0119]; Fig. 3A-3F).

(S) As per previously presented claim 66, *Fletcher* discloses the system of claim 49, wherein the reader comprises a touch pad for entering the request for information logged into the system computer (*Fletcher*: par. [0057]).

Examiner has noted insofar as claim 66 recites "at least one of a touch pad, a keypad, an optical scanner and a magnetic scanner," a touch pad (i.e., touch screen) has been recited.

(T) As per previously presented claim 67, *Fletcher* discloses the system of claim 49, further comprising a report generated by the blood component collection application and displayed via the interface, wherein the report provides blood component collection facility information associated with the donor (*Fletcher*: par. [0012], [0026], [0030] and [0075]).

(U) As per previously presented claim 68, *Fletcher* discloses the system of claim 49 comprising a report generated by the blood component collection application and

displayed via the interface, wherein the report for provides blood component collection facility information associated to the blood component collection kit (*Fletcher*: par. [0012], [0026], [0030], [0022], [0075], [0125]; Fig. 6A-6D).

(V) As per previously presented claim 69, *Fletcher* discloses the system of claim 49, further comprising a remote server operably connected to the system computer via a communication network, wherein the remote server monitors and tracks a remote blood collection facility (*Fletcher*: par. [0012]; Fig. 1A-1D).

(W) As per previously presented claim 70, *Fletcher* discloses the system of claim 69, wherein a second interface provides access to the remote server through a browser within the second interface (*Fletcher*: par. [0012], [0030] and [0194]).

(X) As per previously presented claim 71, *Fletcher* discloses the system of claim 69, wherein a second interface provides access to data received by the system computer from the remote server (*Fletcher*: par. [0012] and [0030]).

(Y) As per previously presented claim 72, *Fletcher* discloses the system of claim 50, wherein blood-component-collection-initialization code segment requests a blood component instrument identifier (*Fletcher*: par. [0012], [0069] and [0159]; Fig. 5A).

(Z) As per previously presented claim 73, *Fletcher* discloses the system of claim 72, wherein the blood-component-collection-initialization code segment further requests a blood component collection process identifier (*Fletcher*: par. [0012], [0019], [0069] and Fig. 6E).

(AA) As per previously presented claim 74, *Fletcher* discloses the system of claim 73, wherein the blood-component-collection-initialization code segment further requests the donor identifier (*Fletcher*: par. [0012], [0069], and [0167]; Fig. 6A).

(BB) As per previously presented claim 75, *Fletcher* discloses the system of claim 74, wherein the blood-component-collection-initialization code segment further requests the operator identifier (*Fletcher*: par. [0012], [0069], and [0079]; Fig. 6D).

(CC) As per previously presented claim 76, *Fletcher* discloses the system of claim 50, wherein the arm-prep code segment further requests an anatomical location on the donor for drawing the blood component (*Fletcher*: par. [0019], [0086], [0094], [0157], [0160] and [0166] and [0182]).

Examiner notes also that *Fletcher* teaches the use of dialog boxes to record comments (e.g., location on donor where the blood component was or is to be drawn from) regarding all phases of the blood collection process.

(DD) Previously presented claim 77-86 substantially repeat the same limitations of claims 72-75 and therefore, are rejected for the same reasons given for those claims.

(EE) As per previously presented claim 87, *Fletcher* discloses the system of claim 86, wherein the remove-blood-component code segment further requests confirmation of a calculated amount of blood component to be removed and an actual amount of blood component removed (*Fletcher*: par. [0177], [0184] and [0185]; Fig. 3C-6M).

(FF) As per previously presented claim 88, *Fletcher* discloses the system of claim 87, wherein the remove-blood-component code segment further requests a reason for a difference between the calculated amount of blood component to be removed and the actual amount of blood component removed (*Fletcher*: par. [0018], [0075], [0086], [0094], [0157], [0160] and [0166] and [0182]).

Examiner notes that *Fletcher* teaches the use of dialog boxes to record comments (e.g., discrepancies between calculated and actual amounts of blood collected) regarding various phases of the blood collection process.

(GG) As per previously presented claim 89, *Fletcher* discloses the system of claim 88, wherein the disconnect-blood-component-donor code segment further requests the operator identifier of the operator administering the disconnect-blood-component-donor procedure (*Fletcher*: par. [0012], [0069], [0079], and [0191]; Fig. 6D).

(HH) As per previously presented claim 90, *Fletcher* discloses the system of claim 50, wherein the disconnect-blood-component-donor code segment further requests a reaction of the blood donor during the blood component collection process (*Fletcher*: par. [0019], [0086], [0094], [0157], [0160] and [0166] and [0182]).

Examiner notes that *Fletcher* teaches the use of dialog boxes to record comments (e.g., donor reactions during the blood collection process) regarding various phases of the blood collection process.

(II) As per previously presented claim 91, *Fletcher* discloses the system of claim 49, further comprising an alarm generated by the blood component collection application and displayed via the interface for alerting the operator of a condition affecting the blood component collection process (*Fletcher*: par. [0019], [0155], [0158], [0159], [0163], and [0182]).

(JJ) Previously presented claim 92 repeats the same limitations of claim 91 and is therefore, rejected for the same reasons given for claim 91.

(KK) As per previously presented claim 93, *Fletcher* discloses the system of claim 49, wherein blood component collection application comprises at least one code segment for receiving data, the data selected from instrument set-up data (*Fletcher*: par. [0014] and [0072]; Fig. 3A-3F).

Examiner has noted insofar as claim 93 recites "at least one code segment for receiving data, the data selected from a group consisting of clearing instrument alarm data, clearing instrument alert data, instrument set-up data, soft good data, program procedure data, arm-prep data, venipuncture data, remove plasma data, disconnect data, saline data, donor reaction data, re-sync data, move donor data, procedure termination data, change component data, maintenance data, field service data, out-of-service data, and in-service data," instrument set-up data has been recited.

(LL) Previously presented claim 94 and 95 substantially repeat the same limitations as claims 75 and 72, respectively and therefore, are rejected for the same reasons given for those claims.

(MM) As per previously presented claim 96, *Fletcher* discloses the system of claim 93, wherein the at least one code segment associates the operator identifier with the data (*Fletcher*: par. [0018] and [0179]; Fig. 6A-6J).

(NN) As per previously presented claim 97, *Fletcher* discloses the system of claim 93, wherein the at least one code segment associates a blood component collection instrument identifier with the data (*Fletcher*: par. [0159]; 6A-6J).

(OO) Claims 98-143 substantially repeat the same limitations as those of claims 49-84, 86-91 and 93-97 and therefore, are rejected for the same reasons given for those claims and incorporated herein.

Response to Arguments

4. Applicant's arguments filed 9/20/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 9/20/07.

(A) On pages 21-23 of the 9/20/07 response, Applicant argues that neither *Fletcher* nor *Brierton* disclose or teach a software arm-prep code segment and the logging in of the arm-prep procedure.

First, Examiner respectfully submits that the combined teachings of *Fletcher* and *Brierton*, *in toto*, do indeed disclose, teach and suggest Applicant's aforementioned features. For example, *Brierton* discloses a donor/patient prep screen that pictorially conveys to the operator the steps that must be undertaken in relation to the donor/patient being fluidly interconnected with the blood-processing device (*Brierton*: col. 57, line 63-col. 58, line 14). Moreover, *Brierton* clearly discloses an arm prep phase associated with the donor/patient (*Brierton*: Fig. 37). Furthermore, the blood-processing system disclosed by Brierton is a computerized software based system with an intricate graphical user interface (GUI) that "walks" the user through a blood-processing

procedure. Ergo, a skilled artisan would be readily apprised that the Brierton system runs on a plurality of "code segments," such as an "arm-prep code segment."

Second, assuming arguendo that neither Fletcher nor Brierton disclose, teach or suggest, the aforementioned features claimed by Applicant, Examiner notes that Moreover, Examiner notes that merely automating a manual activity (e.g., turning a system on or off) is not sufficient to distinguish Applicant's claimed invention over the prior art. *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

(B) Applicant's remaining arguments in the response filed 9/20/07 rely on or re-hash the issues addressed above and therefore, are moot in view of the responses given above and incorporated herein.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MT

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